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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,642	02/01/2002	Richard Fayerer-Hosken	235.00310101	1056
26813	7590	07/01/2004		EXAMINER
MUETING, RAASCH & GEBHARDT, P.A. P.O. BOX 581415 MINNEAPOLIS, MN 55458			SZPERKA, MICHAEL EDWARD	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/019,642	FAYRER-HOSKEN ET AL.
	Examiner	Art Unit
	Michael E Szperka	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) ____ is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____ . |

DETAILED ACTION

Election/Restrictions

- 1 Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-11, drawn to a fertility impairing vaccine comprising an avian zona pellucida protein or an immunogenic fragment thereof.

Group II, claims 1, 6-8, and 10-16, drawn to a fertility impairing vaccine comprising a polynucleotide that encodes an avian zona pellucida protein or encodes an immunogenic fragment of said protein.

Group III, claims 1-11, 27, and 28, drawn to a fertility impairing vaccine comprising an avian zona pellucida protein or an immunogenic fragment thereof, and a porcine zona pellucida protein or an immunogenic fragment thereof.

Group IV, claims 1, 6-8, 10-16 and 27, drawn to a fertility impairing vaccine comprising polynucleotides encoding an avian zona pellucida protein or an immunogenic fragment thereof, and polynucleotides encoding a porcine zona pellucida pellucida protein or an immunogenic fragment thereof.

Group V, claims 17-25, drawn to a method of administering a fertility impairing vaccine comprising an avian zona pellucida protein or an immunogenic fragment thereof.

Group VI, claims 17-25, drawn to a method of administering a fertility impairing vaccine comprising a polynucleotide that encodes an avian zona pellucida protein or encodes an immunogenic fragment of said protein.

Group VII, claims 17-25, drawn to a method of administering a fertility impairing vaccine comprising an avian zona pellucida protein or an immunogenic fragment thereof, and a porcine zona pellucida protein or an immunogenic fragment thereof.

Group VIII, claims 17-26, drawn to a method of administering a fertility impairing vaccine comprising polynucleotides encoding an avian zona pellucida protein or an immunogenic fragment thereof, and polynucleotides encoding a porcine zona pellucida pellucida protein or an immunogenic fragment thereof.

2 The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PTC Rule 13.1 because, under PTC Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As was found in the International Search Report, the Inventions of Groups I and III were found to have no special technical feature that defined a contribution over the prior art of M. Waclawek et al., "The chicken homologue of zona pellucida protein 3 is synthesized by granuloma cells" *Biology of Reproduction*, vol. 59, 1998 pages 1230-1239, and T. Tsuda et al., "Isolation and Characterization of Chicken egg coat 97kDa glycoprotein: the chicken homologue of zona pellucida glycoprotein B (ZPB)" *Zygote*, vol. 6, supplement 1, 1998 pages 94-95.

Waclewek et al. teaches a partial sequence of avian zona pellucida protein 3 while Tsuda et al. teaches the isolation and characteristics of the chicken homolog of ZPB. As Applicants do not indicate a specific avian zona pellucida protein, claims 1-5 are anticipated by these references.

Since Applicant's Inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

Further, it is noted that the claims are drawn to patentably distinct products that differ in structure, and methods for administering said distinct products. For

examination purposes the distinct products are a polypeptide vaccine derived from an avian source, a polynucleotide vaccine derived from an avian source, a polypeptide vaccine derived from avian and porcine sources, and a polynucleotide vaccine derived from avian and porcine sources. If Applicant claims other products or combinations of products, the claims will be subject to further restriction. Therefore, the restriction is set forth for each of the various groups, irrespective of the format of the claims.

3. For examination purposes the following is noted:

This application contains claims directed to the following patentably distinct species of the claimed inventions of Groups V-VIII in that they encompass a method of vaccination that can be performed on many mammals. Applicant is required to elect one mammal for the method of vaccination from the following list:

- a) horse,
- b) deer,
- c) elephant,
- d) rat,
- e) mouse,
- f) rabbit,
- g) ferret,
- h) dog, or
- i) cat.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, currently claims 17 and 21 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. The examiner has required restriction between product and process claims.
Where applicant elects claims directed to the product, and a product claim is

subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after allowance are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer*, and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 22, 2004

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6/24/04